DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

April 22, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: In re Korangy Radiology Associates, P.A., et al.
FDA Docket No. 2003H-0432

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and one copy of Complainant's Proposed Findings of Fact, Conclusions of Law, and Order.

If you have any questions, please call me at (301) 827-7138. Thank you.

Sincerely yours,

Douglas A. Terry
Assistant Chief Counsel
for Enforcement

Enclosure

cc w/enc.:

Hon. Daniel J. Davidson, A.L.J.
Henry E. Schwartz

2003H-0432

FF1

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of KORANGY RADIOLOGY ASSOCIATES, P.A., trading as BALTIMORE IMAGING CENTERS, a corporation, and AMILE A. KORANGY, M.D., an individual.	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY FDA Docket: 2003H-0432

PROPOSED FINDINGS OF FACT,
CONCLUSIONS OF LAW, AND ORDER

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), brought this action for administrative civil money penalties against Respondents Korangy Radiology Associates, P.A., and Amile A. Korangy, M.D., alleging violations of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. Complainant filed Complainant's Motion For Partial Summary Judgment (Complainant's Motion) on April 2, 2004, moving for partial summary judgment on the issue of Respondents' liability for these violations. Complainant's Motion having been fully briefed, the Presiding Officer now makes the following findings of fact and conclusions of law:

FINDINGS OF FACT

1. Respondent Korangy Radiology Associates is a professional corporation organized and existing under the laws of the state of Maryland. See Answer of Respondents, Korangy

Radiology Associates, P.A., T/A Baltimore Imaging Centers, and Amile A. Korangy, M.D. (Answer) ¶ 3.

2. Korangy Radiology Associates is engaged in the business of conducting mammography examinations, and it owns and operates a mammography facility doing business as Baltimore Imaging Centers (BIC) at 724 Maiden Choice Lane, Suite 102, Catonsville, Maryland 21228. Id.

3. Respondent Amile A. Korangy, M.D., is the President, Director, and sole owner of Korangy Radiology Associates. See Stock Purchase Agreement, dated October 30, 1998 (attached as Ex. G-A to Complainant's Motion); Informal Action of the Stockholders and Board of Directors of Drs. Wityk, Goad, Korangy & Associates, P.A., dated October 30, 1998 (attached as Ex. G-B to Complainant's Motion); Certified Copy of Articles of Amendment, Drs. Wityk, Goad, Korangy & Associates, P.A., dated December 10, 1998 (attached as Ex. G-C to Complainant's Motion).

4. Dr. Korangy is also the Supervising Radiologist and Lead Interpreting Physician of the BIC mammography facility. Declaration of Michael P. Divine, M.S. (Divine Decl.; attached as Ex. G-D to Complainant's Motion) ¶ 17 and Ex. G-6 thereto at 1, 3, 6; Declaration of Elizabeth A. Laudig (Laudig Decl.; attached as Ex. G-E to Complainant's Motion) ¶ 8.

5. Dr. Korangy directs the "day-to-day" operations of BIC and is responsible for maintaining BIC's certification under the

MQSA. Laudig Decl. ¶ 8; Divine Decl. ¶ 17 and Ex. G-6 thereto.

6. FDA issued a mammography certificate to Respondents on May 6, 1999. Divine Decl. ¶ 11 and Ex. G-4 thereto. The certificate, which enabled Respondents to lawfully perform mammography at the BIC facility, was scheduled to expire on May 6, 2002.[1] Id.

7. FDA advised Respondents by letter dated April 1, 2002, that BIC's certificate would expire on May 6, 2002, unless BIC was re-accredited by an FDA-approved accreditation body. Divine Decl. ¶ 11 and Ex. G-1 thereto. The letter also informed Respondents that BIC could no longer perform mammography services once its certificate expired. Id.

8. By letter dated April 29, 2002, the American College of Radiology (ACR), an FDA-approved accreditation body, informed Respondents that BIC failed to qualify for re-accreditation as a mammography facility. Id. ¶ 12 and Ex. G-2 thereto. As the basis for this decision, ACR found that the mammograms produced by BIC failed to comply with ACR's standards for clinical image quality. Id. ACR also strongly recommended that BIC immediately cease performing mammography examinations.[2] Id.

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[1]A certificate is effective for a period of three years after the date that it is issued or renewed. 42 U.S.C. § 263b(c)(1); Divine Decl. ¶ 9.

[2]Although ACR denies accreditation when a facility fails to meet accreditation standards, it is FDA that brings enforcement actions against entities and individuals that violate the MQSA. Divine Decl. ¶ 9.

9. Dr. Korangy discussed the April 29, 2002, letter from ACR with Barry J. Henderson, BIC's Vice President. See Laudig Decl. ¶ 11 and Ex. G-11 thereto. Dr. Korangy and Mr. Henderson decided that the mammograms produced by BIC were acceptable, and that BIC would continue to perform examinations. Id.

10. By letter dated May 1, 2002, FDA confirmed to Respondents that BIC had been denied accreditation due to its failure to meet ACR accreditation standards.[3] Divine Decl. ¶ 13 and Ex. G-3 thereto. Accordingly, FDA advised that it was unable to recertify BIC as a mammography facility and instructed Respondents to cease performing mammography. Id.

11. BIC's certificate expired on May 6, 2002. Divine Decl. ¶ 14 and Ex. G-4 thereto.

12. On July 18, 2002, ACR sent a letter to Complainant describing ACR's concern that, despite its lack of certification, BIC was continuing to perform mammography. Id. ¶ 15 and Ex. G-5 thereto. As a result of this letter, Complainant contacted FDA's Baltimore District Office and requested that it conduct an inspection of BIC. Id. ¶ 16.

13. Respondents installed a new mammography unit in the BIC facility on or around June 28, 2002. Laudig Decl. ¶ 13 and Ex. G-12 thereto.

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[3]A technologist at BIC named "Sonier" signed for the receipt of FDA's May 1, 2002, letter to Dr. Korangy. Laudig Decl. ¶ 12; Divine Decl. ¶ 13 and Ex. G-3 thereto.

14. Several weeks later, on July 22, 2002, Dr. Korangy applied for reinstatment of BIC's accreditation by submitting a reinstatement application to ACR. See Answer ¶ 16; Divine Decl. ¶ 17 and Exhibits G-6 and G-7 thereto. In the application, Dr. Korangy indicated that BIC had corrected its clinical image deficiencies by, among other things, purchasing a new mammography unit. Divine Decl. ¶ 17 and Exhibits G-6 and G-7 thereto.

15. On July 24, 2002, ACR notified FDA that BIC's application for accreditation reinstatement was sufficiently complete for review, and that BIC was eligible for provisional reinstatement. Id. ¶ 18.

16. On July 26, 2002, FDA issued a provisional certificate to BIC and informed Dr. Korangy that BIC was certified to lawfully provide mammography services. See Answer ¶ 17; Divine Decl. ¶ 19 and Exhibits G-8 and G-9 thereto.

17. FDA investigators conducted an inspection of BIC during August 8, 12, 21-22, and September 3, 5-6, 2002. Laudig Decl. ¶ 5. The purpose of the inspection was to determine whether Respondents had performed mammography without a valid certificate. Id.

18. During the inspection, the investigators collected documents for mammography examinations that Respondents conducted between May 7, 2002, and July 25, 2002, the period in which BIC was uncertified to perform mammography. Laudig Decl. ¶ 10;

Divine Decl. ¶ 21 and Ex. G-10 thereto.

19. These reports show that Respondents conducted 192 mammography examinations, while they were uncertified, between and including May 7, 2002, and July 25, 2002. Divine Decl. ¶ 21.

CONCLUSIONS OF LAW

20. Under the regulations governing this action, "a party may move . . . for a summary decision on any issue in the hearing." 21 C.F.R. § 17.17(a). The Presiding Officer "shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue of material fact and that the party is entitled to summary decision as a matter of law." 21 C.F.R. § 17.17(b).

21. Furthermore, where "a motion for summary decision is made and supported as provided in [21 C.F.R. § 17.17], a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing." 21 C.F.R. § 17.17(c).

22. The MQSA was enacted to establish uniform mammography standards and a certification process to ensure that only those mammography facilities providing high quality mammograms would remain in operation. See 62 Fed. Reg. 55852 (Oct. 28, 1997).

The MQSA became effective on October 1, 1994. Id.

23. Under the MQSA, no mammography facility may conduct a mammography examination or procedure unless it possesses an effective certificate that has been issued or renewed under the MQSA. 42 U.S.C. § 263b(b)(1).

24. In order to obtain or renew a certificate, the MQSA, and its implementing regulations, require a facility to apply to, and be accredited by, an FDA-approved accreditation body. 42 U.S.C. § 263b(d)(1)(A)(iv); 21 C.F.R. §§ 900.11(a) and (b). Once FDA receives notification of the accreditation body's decision to accredit a facility, FDA may issue a certificate to the facility or renew the facility's existing certificate. 21 C.F.R. § 900.11(b)(ii).

25. Where a previously certified facility has allowed its certificate to expire or has been refused a renewal, as in this case, the facility may apply to an accreditation body to have its certificate reinstated. 21 C.F.R. § 900.11(c). FDA may issue a provisional certificate to the facility once the accreditation body notifies FDA that the facility has corrected the deficiencies that led to the lapse of its certificate. 21 C.F.R. § 900.11(c)(2). A facility may lawfully perform mammography services once it receives a provisional certificate. 21 C.F.R. § 900.11(c)(3).

26. No genuine issue of material fact exists as to whether

Respondents Korangy Radiology Associates and Dr. Korangy violated the MQSA.

27. The undisputed facts show that each Respondent is liable for 193 violations of the MQSA. Each Respondent is liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A), and for 192 violations pursuant to 42 U.S.C. § 263b(h)(3)(D).

A. Korangy Radiology Associates

1. Failure To Obtain A Certificate

28. Under 42 U.S.C. § 263b(h)(3)(A), FDA may assess civil money penalties for a "failure to obtain a certificate as required by" 42 U.S.C. § 263b(b).

29. The MQSA places the duty of obtaining a certificate upon the owner or lessee of the facility, or an authorized agent of either. 42 U.S.C. § 263b(d)(1).

30. Korangy Radiology Associates is the owner of the BIC facility.

31. Korangy Radiology Associates failed to obtain a certificate for the period between and including May 7, 2002, and July 25, 2002, during which BIC performed mammography in violation of 42 U.S.C. § 263b(b)(1). Korangy Radiology Associates is therefore liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A).

2. Performance Of 192 Uncertified Mammography Examinations

32. Under 42 U.S.C. § 263b(h)(3)(D), FDA may assess civil money penalties in an amount not to exceed $10,000 for each violation of, or for aiding and abetting in a violation of, any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate.

33. Between and including May 7, 2002, and July 25, 2002, Korangy Radiology Associates conducted 192 mammography examinations while the BIC mammography facility was uncertified, in violation of 42 U.S.C. § 263b(b)(1).

34. Accordingly, Korangy Radiology Associates is liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D).

B. Dr. Korangy

35. Dr. Korangy, as the sole owner and most responsible person at Korangy Radiology Associates, is liable for violating the MQSA to the same extent as Korangy Radiology Associates.

36. It is well established that responsible corporate officers are individually liable for violations of public health legislation. See United States v. Dotterweich, 320 U.S. 277, 285, 64 S.Ct. 134, 138 (1943); United States v. Park, 421 U.S. 658, 672, 95 S.Ct. 1903, 1911 (1975); United States v. Hodges X-Ray, Inc., 759 F.2d 557, 560 (6th Cir. 1985); United States v. DeHaven and Assoc., Inc., No. 95-1177, 1996 U.S. Dist. LEXIS 22355, at *12 (E.D. La. Feb. 9, 1996).

37. Accordingly, a corporate officer who is in a position to prevent violations of statutes affecting public health is personally responsible for such violations. See Park, 421 U.S. at 673-74, 95 S. Ct. at 1912; see also DeHaven and Assoc., Inc., 1996 U.S. Dist. LEXIS 22355, at *12.

38. Dr. Korangy is the President, Director, and sole owner of Korangy Radiology Associates, the owner of the BIC mammography facility. Dr. Korangy has the authority to determine whether Korangy Radiology Associates, and its physicians, continue to perform mammography. Dr. Korangy, by virtue of his position, had the authority to prevent Korangy Radiology Associates from performing uncertified mammography examinations in violation of 42 U.S.C. § 263b(b)(1).

39. Because he failed to prevent these violations, Dr. Korangy is liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A) for failing to obtain a certificate. Dr. Korangy is also liable, as the owner of, and most responsible person at, Korangy Radiology Associates, for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D).

40. As an alternative ground for holding Dr. Korangy liable for 193 violations of the MQSA, Dr. Korangy aided and abetted Korangy Radiology Associates in failing to obtain a certificate and in performing 192 uncertified mammography examinations.

41. A person is liable as an aider and abettor if (1) the

underlying violation was committed by a principal; (2) the person knew of the violation; and (3) the person participated or assisted in the execution of the violation. Cf. United States v. Keene, 341 F.3d 78, 84 (1st Cir. 2003); United States v. Ramirez-Velasquez, 322 F.3d 868, 880 (5th Cir. 2003); United States v. Davis, 306 F.3d 398, 401 (6th Cir. 2002); United States v. Hunt, 272 F.3d 488, 493 (7th Cir. 2001) (all interpreting "aiding and abetting" under 18 U.S.C. § 2, which makes punishable as a principal one who aids or abets the commission of a federal offense).

42. Dr. Korangy aided and abetted Korangy Radiology Associates in conducting 192 examinations while the BIC facility was uncertified, in violation of 42 U.S.C. § 263b(b)(1).

43. Dr. Korangy knew that Korangy Radiology Associates was performing mammography without a certificate. FDA advised Dr. Korangy by letter dated April 1, 2002, that BIC's certificate would expire on May 6, 2002, and that BIC could no longer perform mammography once the certificate expired. By letter dated April 29, 2002, ACR informed Dr. Korangy that BIC failed to qualify for re-accreditation due to the poor clinical image quality of its mammograms. Dr. Korangy disregarded the information from the accreditation body and continued to perform mammography. By letter dated May 1, 2002, FDA confirmed to Dr. Korangy that it was unable to renew BIC's certificate due to BIC's failure to

obtain accreditation. In addition, BIC's certificate stated that it expired on May 6, 2002. It is inconceivable that Dr. Korangy was unaware that BIC lacked certification between and including May 7, 2002, and July 25, 2002.

44. Dr. Korangy participated and assisted in the performance of uncertified mammography examinations. Dr. Korangy himself read and interpreted the mammograms from at least 116 of the uncertified examinations. Divine Decl. ¶ 21 and Ex. G-10 thereto. The mammograms from the remaining uncertified examinations were read and interpreted by Irfan S. Shafique, M.D., and Robert J. Hage, D.O. Id. Dr. Korangy, however, remains liable for aiding and abetting with respect to these examinations because he possessed the authority to decide whether Drs. Shafique and Hage performed them.

45. Dr. Korangy is liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D), and for one (1) violation pursuant to 42 U.S.C. § 263b(h)(3)(A) for failing to obtain a certificate.

* * *

Accordingly, it is ORDERED, ADJUDGED, AND DECREED, that:

Complainant's Motion For Partial Summary Judgment is GRANTED;

Respondents Korangy Radiology Associates and Dr. Korangy are each liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A);

Respondents Korangy Radiology Associates and Dr. Korangy are each liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D); and thus

Respondents Korangy Radiology Associates and Dr. Korangy are each liable for 193 violations of the MQSA.

Further appropriate proceedings regarding the appropriate amount of the penalties will follow.

Daniel J. Davidson
Administrative Law Judge
U.S. Food and Drug Administration
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Proposed by:

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CERTIFICATE OF SERVICE

I hereby certify that, on this 22nd day of April, 2004, I have caused a copy of the foregoing Proposed Findings Of Fact, Conclusions Of Law, And Order to be served by Federal Express overnight delivery, on:

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